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CARAFATE®
sucralfate/Marion

BRIEF SUMMARY

CONTRAINDICATIONS
There are no known contraindications to the use of sucralfate.

PRECAUTIONS
Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that the simultaneous administration of CARAFATE with tetracycline, phenytoin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. The clinical significance of these animal studies is yet to be defined.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related tumorigenicity was found in chronic oral toxicity studies of 24 months' duration conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies have not been conducted.

Pregnancy: Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS
Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients, adverse effects were reported in 121 (4.7%). Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

DOSAGE AND ADMINISTRATION
The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

HOW SUPPLIED
CARAFATE (sucralfate) 1-gm pink tablets are supplied in bottles of 100 and in Unit Dose Identification Paks of 100. The tablets are embossed with MARION/1712. Issued 3/84

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Meclomen® (meclofenamate sodium capsules, USP)
Before prescribing, please see full prescribing information.
A Brief Summary follows.

CONTRAINDICATIONS: Patients who have previously exhibited Meclomen hypersensitivity or in whom aspirin or other nonsteroidal antiinflammatory drugs (NSAIDs) induce symptoms of bronchospasm, allergic rhinitis, or urticaria. **WARNINGS:** In patients with a history of upper gastrointestinal (GI) tract disease, Meclomen should be given under close supervision (see Adverse Reactions section). Peptic ulceration and GI bleeding, sometimes severe, including one fatality, have been reported. **PRECAUTIONS: General:** Patients receiving NSAIDs should be evaluated periodically to insure that the drug is still necessary and well tolerated (see other Precautions, Warnings and Adverse Reactions). Diarrhea, GI irritation and abdominal pain may be associated with Meclomen therapy. Dosage reduction or temporary discontinuation generally control these symptoms (see Adverse Reactions and Dosage and Administration sections). Decreases in hemoglobin and/or hematocrit levels have occurred in approximately 1 of 6 patients, but rarely required discontinuation of therapy. The clinical data revealed no evidence of increased chronic blood loss, bone marrow suppression, or hemolysis to account for decreases in Hb or Hct levels. Patients receiving long-term Meclomen therapy should have Hb and Hct values determined if anemia is suspected on clinical grounds. If a patient develops visual symptoms (see Adverse Reactions) during therapy, the drug should be discontinued and the patient should have a complete ophthalmologic examination. When Meclomen is used in combination with steroid therapy, any reduction in steroid dosage should be gradual to avoid possible complications of sudden steroid withdrawal. Adverse effects are seen more commonly in the elderly; a lower starting dose and careful follow-up are advised. As with other NSAIDs, borderline elevations of one or more liver tests may occur in some patients. These abnormalities may progress, remain essentially unchanged, or be transient with continued therapy. The SGPT (ALT) test is probably the most sensitive indicator of liver dysfunction. Meaningful (3 times the upper limit of normal) elevations of SGPT or SGOT (AST) occurred in controlled clinical trials in less than 1% of patients. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of more severe hepatic reaction while on therapy with Meclomen. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with other NSAIDs. Although such reactions are rare, if abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (eg, eosinophilia, rash), Meclomen should be discontinued. **Renal Effects:** As with other NSAIDs, long-term administration of meclofenamate sodium to animals has resulted in renal papillary necrosis and other abnormal renal pathology. In humans, there have been reports of acute interstitial nephritis with hematuria, proteinuria, and occasionally nephrotic syndrome. A second form of renal toxicity has been seen in patients with prerenal conditions leading to a reduction in renal blood flow or blood volume, where the renal prostaglandins (PGs) have a supportive role in the maintenance of renal perfusion. In these patients administration of an NSAID may cause a dose-dependent reduction in PG formation and may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics, and the elderly. Discontinuation of NSAID therapy is typically followed by recovery to the pretreatment state. Since Meclomen is eliminated by the kidneys, patients with significantly impaired renal function should be closely monitored; lower daily dosage should be anticipated to avoid excessive drug accumulation. **Information for Patients:** Patients should be advised that nausea, vomiting, diarrhea and abdominal pain have been associated with the use of Meclomen and accordingly should consider discontinuing the drug and contacting his/her physician if any of these conditions are severe. Meclomen may be taken with meals or milk to control GI complaints. Concomitant administration of an antacid (specifically, aluminum and magnesium hydroxides) does not interfere with absorption of the drug. **Laboratory Tests:** Patients receiving long-term Meclomen therapy should have Hb and Hct values determined if signs or symptoms of anemia occur. Low WBC counts were rarely observed in clinical trials. These low counts were transient and usually returned to normal while the patient continued on therapy. Persistent leukopenia, granulocytopenia, or thrombocytopenia warrants further clinical evaluation and may require discontinuation of the drug. When abnormal blood chemistry values are obtained, follow-up studies are indicated. Elevations of serum transaminase levels and of alkaline phosphatase levels occurred in approximately 4% of patients. An occasional patient had elevations of serum creatinine or BUN levels. **Drug Interactions: 1. Warfarin:** Meclomen enhances the effect of warfarin. Used concomitantly, the dosage of warfarin should be reduced to prevent excessive prolongation of the prothrombin time. **2. Aspirin:** Concurrent administration of aspirin may lower Meclomen plasma levels. Urinary excretion is unaffected by aspirin, indicating no change in Meclomen absorption. Meclomen does not affect serum salicylate levels. Greater fecal blood loss results from concomitant administration than from either drug alone. **3. Propoxyphene:** Concurrent administration of propoxyphene HCl does not affect Meclomen bioavailability. **4. Antacids:** Concomitant administration of aluminum and magnesium hydroxides does not interfere with Meclomen absorption. **Carcinogenesis:** An 18-month study in rats revealed no evidence of carcinogenicity. **Pregnancy and Nursing Mothers:** Because there are no adequate and well-controlled studies in pregnant women and it is not known whether the drug is excreted in human milk, Meclomen is not recommended for use during pregnancy (particularly in the 1st and 3rd trimesters) or in nursing women, based on animal findings. **Pediatric Use:** Safety and efficacy in children under age 14 have not been established. **ADVERSE REACTIONS: Incidence Greater than 1%:** The following adverse reactions were observed in clinical trials and included observations from more than 2,700 patients (594 treated for 1 year and 248 for at least 2 years): **GI:** The most frequently reported adverse reactions associated with Meclomen involve the gastrointestinal system: Diarrhea (10%-33%), nausea with or without vomiting (11%), other gastrointestinal disorders (10%), abdominal pain,* pyrosis,* flatulence,* anorexia, constipation, stomatitis and peptic ulcer. **Cardiovascular:** Edema. **Dermatologic:** Rash,* urticaria, pruritus. **CNS:** Headache,* dizziness.* **Special Senses:** Tinnitus. **Incidence Less than 1% (Probably Causally Related):** The following adverse reactions were reported less frequently than 1% during controlled clinical trials and through voluntary reports since marketing. The probability of a causal relationship exists between the drug and these adverse reactions. **GI:** Bleeding and/or perforation with or without obvious ulcer formation, colitis, cholestatic jaundice. **Renal:** Renal failure. **Hematologic:** Neutropenia, thrombocytopenic purpura, leukopenia, agranulocytosis, hemolytic anemia, eosinophilia, decrease in Hb and/or Hct. **Dermatologic:** Erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis. **Hepatic:** Alteration of liver function tests. **Allergic:** Lupus and serum sickness-like symptoms. **Incidence Less than 1% (Causal Relationship Unknown):** Other reactions have been reported but under conditions where a causal relationship could not be established. However, in these rarely reported events, that possibility cannot be excluded. Therefore, these observations are listed to alert physicians. **Cardiovascular:** Palpitations. **CNS:** Malaise, fatigue, paresthesia, insomnia, depression. **Special Senses:** Blurred vision, taste disturbances, decreased visual acuity, temporary loss of vision, reversible loss of color vision, retinal changes including macular fibrosis, macular and perimacular edema, conjunctivitis, iritis. **Renal:** Nocturia. **GI:** Paralytic ileus. **Dermatologic:** Erythema nodosum, hair loss. **OVERDOSAGE:** After a massive overdose, CNS stimulation may be manifested by irrational behavior, marked agitation and generalized seizures. Renal toxicity may be noted with possible oliguria or anuria and azotemia. Management consists of emptying the stomach by emesis or lavage and instilling an ample dose of activated charcoal into the stomach. Seizures should be controlled by an appropriate anticonvulsant regimen. Dialysis may be required to correct serious azotemia or electrolyte imbalance. **Caution**—Federal law prohibits dispensing without prescription.

*Incidence between 3% and 9%. Those reactions occurring in 1%-3% of patients are unmarked.

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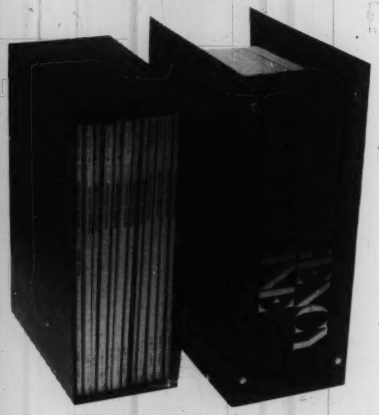

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